



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Testimony of the National Association of Chain Drug Stores

on

Connecticut Raised Bill No. 5307

Before

The

Joint Committee on Public Health

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For the Hearing

On

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TO: The Honorable Members of the Public Health Committee

On behalf of its members operating chain pharmacies in the state of Connecticut, the National Association of Chain Drug Stores (NACDS) submits this testimony to express our concerns regarding Raised Bill Number 5307. The legislation would prohibit a pharmacy filling or refilling a prescription for the treatment of epilepsy or prevention of seizures from substituting an antiepileptic drug or a formulation of an antiepileptic drug, brand name or manufacturer of a generic name unless the pharmacist provides prior notice to the patient's practitioner and obtains the consent of the patient's practitioner to do so. We cannot support this legislation as it adds unnecessary duplicative requirements as prescribers already have authority to prescribe for their patients and could have adverse consequences for the delivery of pharmacy care to Connecticut residents and delay necessary treatment. We thank you for consideration of our submitted comments.

Connecticut Law Already Provides Prescribers and Patients with the Means to address Drug Substitution with FDA Approved Therapeutically Equivalent Drugs

Under Connecticut law, the pharmacist may dispense a therapeutically equivalent generic Food and Drug Administration (FDA) approved drug unless the patient instructs otherwise, and the prescribing practitioner has authority to specify "brand medically necessary" or a particular drug manufacturer. Additional, special requirements on top of these requirements are unnecessarily duplicative and serve no purpose other than to potentially disrupt drug treatment, cause delays in therapy, and discourage pharmacists from providing cost saving generic drugs to patients.

Requiring unworkable logistical challenges for pharmacists to provide facsimile notice to the prescriber and to obtain written consent of the prescriber would likely delay the delivery of prescription drugs. Pharmacists would have to wait for the written consent which could take days. Such delays are more than an inconvenience to patients. For epileptics who must strictly comply with their medication regime, delays in drug therapy can have immediate and serious health consequences. Moreover, the addition of the provision related to the pharmacist's professional judgment is not the answer. Treatment would still be delayed while pharmacists attempt to reach the practitioner and pharmacists would likely be reluctant to dispense an alternate drug without the practitioner's authorization.

Contrary to Established FDA Determination of Approved Therapeutically Equivalent Drugs

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The Food and Drug Administration "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly called the FDA "Orange Book") informs pharmacists and other health care providers of generic drugs that the FDA has determined are equivalent to the brand drug product and interchangeable. These generically equivalent drug products are approved by the FDA and deemed equivalent and substitutable for the corresponding brand drug product. FDA's Office of Generic Drugs provides that FDA-approved generic drug products perform the same as the corresponding brand drug product. The FDA website provides information on the agency's review and assurance on the substitution of generic drug products. See http://www.fda.gov/cder/ogd/welcome_to_ogd.htm.

Unwarranted Cost Increases for the Health Care System

Special requirements for dispensing anti-epileptic drugs will result in additional costs to the health care system because higher priced brand drugs would be dispensed where lower cost equivalent generic drugs would be equally effective. It would most likely force pharmacists to fill prescriptions with more expensive brand name products in order to prevent delays and disruptions in the patient's drug treatment. Patients would likely have to pay higher prices whether as copays, other cost-sharing, or the full cost of the drug.

A recent study determined that the impact of this type of legislation would substantially increase prescription drug costs without clinical benefit for consumers.¹ In addition, the study determined that it would lead to substantial costs for payors and state Medicaid programs. The study estimating that the cost for Connecticut for the period from 2010 to 2019 for carving out antiepileptic drugs would be about \$275 million for Medicaid, third party payors, Medicare, and for increased consumers out of pocket costs.

States Have Rejected Carving Out Generic Drugs from the State Drug Substitution Process

FDA has approved thousands of generic drugs since the early 1980's as being bioequivalent to brand name drug products. Congress passed legislation at that time to allow FDA to approve a generic drug product as therapeutically equivalent if the agency determined that it was equivalent to the brand drug product.

In 2008, "carve out" legislation was introduced but not enacted in about 22 states. Only one state, Utah, enacted legislation to place restrictions for anti-epileptic and immunosuppressant drugs. These states recognized that they have well-established

¹ "Undermining Generic Drug Substitution: The Cost of Generic Carve-Out Legislation, A 50 State Analysis Prepared for the Pharmaceutical Care Management Association, October 2008 by Visante.

generic substitution laws and regulations that regulated pharmacist dispensing of generic drugs and that already allow prescribers to specify if a particular drug product is medically necessary. They also recognize that “carve out” legislation would lead to unnecessary increased prescription drug costs.

We urge the Committee to not pass this legislation as now written.
Thank you for consideration of these comments.